0.9% SODIUM CHLORIDE INJECTION - sodium chloride injection, powder, for solution
Fresenius Medical Care North America

0.9% Sodium Chloride Injection, USP is sterile and nonpyrogenic. It is a parenteral solution containing solution chloride in water for injection for intravenous administration.

Each 100 mL of 0.9% Sodium Chloride Injection, USP contains 900 mg sodium chloride in water for injection. Electrolytes per 1000 mL: sodium (Na^+) 154 mEq; chloride (Cl^-) 154 mEq. The osmolarity is 308 mOsmol/L (calc).
The pH is 5.6 (4.5 - 7.0).

This solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only as a single-dose injection. When smaller doses are required, the unused portion should be discarded.

0.9% Sodium Chloride Injection, USP is a parenteral fluid and electrolyte replenisher.

Sodium Chloride Injection, USP is chemically designated NaCl, a white crystalline power freely soluble in water.

Water for Injection, USP is chemically designed H_2O.

The flexible plastic inner bag is fabricated from a specially compounded polyvinylchloride. Water may permeate through the inner bag into the outerwrap in quantities insufficient to significantly affect the solution. Solutions in contact with the plastic inner bag can leach out certain of its chemical components in very small amounts; however, the safety of the plastic formulation is supported by biological testing.

Exposure to temperatures above 25°C (77°F) during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.
When administered intravenously, these solutions provide a source of water and electrolytes.

Solutions which provide combinations of hypotonic or isotonic concentrations of sodium chloride are suitable for parenteral maintenance or replacement of water and electrolyte requirements.

Isotonic concentrations of sodium chloride are suitable for parenteral replacement of chloride losses that exceed or equal the sodium loss. Hypotonic concentrations of sodium chloride are suited for parenteral maintenance of water requirements when only small quantities of salt are desired. A hypertonic concentration of sodium chloride may be used to repair severe salt depletion syndrome.

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. Sodium (Na+) is the principle cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Chloride (Cl^-) has an integral role in buffering action when oxygen and carbon dioxide exchange occurs in the red blood cells. The distribution and excretion of sodium (Na+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirements range from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.
Intravenous solutions containing sodium chloride are indicated for parenteral replenishment of fluid and sodium chloride as required by the clinical condition of the patient.
None known.
Solutions containing sodium ions should be used with great care, if it all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

Excessive administration of potassium-free solutions may result in significant hypokalemia.

In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.

The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states of pulmonary edema.

The risk of dilutional states is inversely proportional to the electrolyte concentrations of administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.
Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions to patients receiving corticosteroids or corticotrophin.

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Carcinogenesis, Mutagenesis, Impairment of Fertility:
Studies have not been performed with Sodium Chloride Injection, USP to evaluate the potential for carcinogenesis, mutagenesis or impairment of fertility.

Pregnancy:
Teratogenic Effects

Pregnancy Category C. Animal reproductive studies have not been conducted with sodium chloride. It is also not known whether sodium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium chloride should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

Caution should be exercised when Sodium Chloride Injection, USP is administered to a nursing women.

Pediatric Use:

The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

Geriatric Use:

Clinical studies of 0.9% Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, exravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

In the event of overhydration or solute overload, re-evaluate the the patient and institute appropriate corrective measures. See WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

The dose is dependent upon the age, weight and clinical condition of the patient.

Drug Interactions:

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS.

INSTRUCTIONS FOR USE

Tear outer wrap at notch and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually.

Check for leaks by squeezing container firmly. If leaks are found discard unit as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administrations.

To Add Medication

(Use aseptic technique)

1. Prepare medication port.

2. With a needle of appropriate length, puncture resealable additive port and inject. Withdraw needle after injecting medication.

3. Mix container contents thoroughly.

Preparation for Administration

(Use aseptic technique)

Note: See appropriate I.V. administration set instructions For Use.

1. Close flow control clamp on the administration set.

2. Remove cap from sterile administration set port at bottom of container by securely grasping the flanges and twisting as indicated below.

3. Insert piercing pin of administration set into port with a twisting motion until the pin is firmly seated.

4. Suspend container.

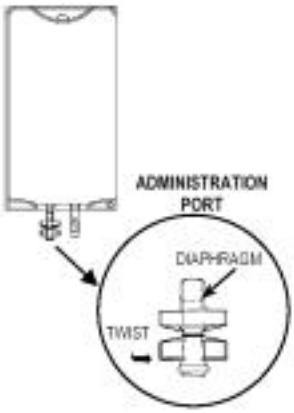
5. If the administration set contains a drip chamber, squeeze and release to establish proper fluid level in chamber.

6. Open clamp. Eliminate air from remainder of set.

7. Attach set to patient access device.

8. Begin infusion.

WARNING: Do not use flexible container in series connections.



0.9% Sodium Chloride Injection, USP is supplied in single-dose flexible plastic containers as follows:

Code	**Product Name**	**Container Size (mL)**	**NDC**
060-10109	0.9% Sodium Chloride Injection, USP	1000	46163-300-10

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. Store at 20^{o} to 25^{o}C (68^{o} to 77^{o}F). [See USP Controlled Room Temperature.] However, brief exposure up to 40^{o}C does not adversely affect the product.

Fresenius Medical Care

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